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EXAMINER

HAMA, JOANNE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

814

Office Action Summary**Application No.**

10/070,597

Applicant(s)

TREFIL ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-3 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 07 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

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Applicant's preliminary amendment filed on March 7, 2002 has been entered. Claims 1-3 are pending and under consideration in the instant action.

This Application is a 371 of PCT/CZ00/00064, filed on September 8, 2000.

This Application claims priority to a foreign application, Czech Republic PV 3186-99, September 8, 1999.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

"then," page 1, line 2 of "Background of the Invention," should be "than."

"cook," page 3, third complete paragraph, line 4, should be "cock."

Appropriate correction is required. Further, applicant should review the specification for additional errors.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, line 1, the claim is to a "method of transgenic fowl construction." According to the Merriam-Webster online dictionary, transgenic means, "having chromosomes into which one or more heterologous genes have been incorporated either artificially or naturally." While the specification discusses the potential for the method in the instant Application to be used to generate transgenic fowl by incorporating heterologous genes into sperm, the specification does not detail how that method is accomplished, nor does it appear

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to be the focus of the Application. Rather, the Application is to a method of sterilizing an acceptor cock's testicles, such that the remainder of the testicle is intact and can provide support for spermatogonia provided by a donor cock.

Perhaps the claim can be rephrased to read, "method of using germline spermatogonial cells for transfer of genetic information...".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of irradiating the acceptor cock's testicles with 8 Gy, 5-times in a week interval, does not reasonably provide enablement for a range of dosages. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

What has been shown in the specification is that 8 Gy, 5-times, in a week interval, was an ideal condition that sterilized, yet maintained the structure of the acceptor cock's testicle. The condition was also ideal because the dose was not lethal to the acceptor cock. What is presented in claim 2 is a range of doses. The claim to a dose of gamma ray of "at least 8 Gy, what is carried out 3-times to 9-times always in 3 to 9 day intervals." "At least 8 Gy" can be read to encompass doses such as 8 Gy, 20 Gy, or 100 Gy. However, according to the specification, one dose of 18 Gy (Example 2, page 9), 22 Gy (Example 3, page 10), and 26 Gy (Example 4, page 10) did not completely sterilize the testicle. Furthermore, at 26 Gy, the dose "influenced health state of this cock negatively (Example 4, first paragraph, 7-8)." In the case of the times of doses, "3-times to 9-times always in 3 to 9 day intervals," the specification does not teach that doses as low as 3-times in 3 days produce completely sterile testicles, nor does it teach that 9-times in 9 days results in sterile testicles that are structurally intact. Furthermore, the claim could encompass testicles that have been irradiated 3-times in 9 days, or 9-times in 3 days. Both extreme cases have not been taught in the specification to produce viable cocks with sterile, structurally intact testicles. Similarly, in claim 3, the testicles are "irradiated with gamma rays up to the absorbed dose 8 Gy always in week intervals." The claim is interpreted to mean that viable cocks with sterile, structurally intact testicles can be made by irradiating cocks with one pulse of 8 Gy a week. The specification has not taught that this dosage was sufficient for producing viable cocks with sterile, structurally intact testicles. One

skilled in the art has not been taught how to reliably make sterile cocks using these methods.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 5-6, the phrase, "the so treated preserved but now sterile testicles" is unclear. The use of the word, "preserved" is confusing because the phrase reads as though the testicles have been treated in a chemical fixative, such as formaldehyde or vinegar. On page 3 of the specification, "preserved" is used to describe the testicle structure (fourth paragraph, lines 5-6). In this case, the spermatogonial cells are completely destroyed, but the testicle structure, including the Sertoli's cells, is intact. Is this the context the Applicant meant by "preserved"? Perhaps, then, the claim should be amended to read, "the sterile, yet structurally intact testicles...".

In claim 1, line 10-12, the phrase, "transgenic fowl offsprings provided to ½ with the donor cock genetic information are breed," is confusing. The phrase reads as though half the offspring chicks are bred from the donor cock. However, according to the specification, due to the nature of the procedure, 100% of the offspring are bred from the donor sperm (page 3, paragraph 5, lines 1-2). Is the claim meant to be read that the offspring chicks obtain half their genetic information from the donor sperm, as described on page 3, first paragraph, lines 5-6? Perhaps the claims should be amended to read, "transgenic offspring obtain half their genetic information from the donor cock."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Brinster (filed May 31, 1996, US Patent No. 5,817,453). Claim 1 is to a method of transplanting donor spermatogonial cells into a male host fowl that had been sterilized by irradiation. The host fowl's testicles, while sterile, was intact such that spermatogonial cells of the donor was able repopulate the testes of the host. For clarification, the first definition of "fowl," taken from the Merriam Webster

Online dictionary, is: “a bird of any kind – compare WATERFOWL, WILDFOWL.”

Brinster's patent is to a technique for freezing spermatogonia cells. However, all the methods described in claim 1 have been described in Brinster. Brinster states in this invention that primitive germs cells are used to repopulate the testes of a male animal host. The recipient animal may then be bred to obtain a novel animal line in which every cell of the descendent animal is genetically non-native to the original recipient host animal (column 3, first paragraph, lines 1-18). Brinster states that radiation is one way of destroying the native germ cell population in the seminiferous tubules. However, radiation leaves intact the supporting cells, including the Sertoli cells (column 5, second paragraph, lines 6-15). Finally, Brinster states that this invention is applicable to any species of animals, including human, in which the male has testes. The invention applies to animals including rodents, birds, and wild and zoo species. Furthermore, Brinster states that his technique can be applied advantageously to farm animals to imbue these animals with genetic modification. Brinster specifically lists chickens and turkeys as birds to which this technology applies (column 10, last paragraph, lines 61-67 to column 11, first paragraph, lines 1-10).

Brinster describes a method for repopulating the testes of a male animal host. Irradiation is one means of destroying the native germ cell population and leaving the supporting cells intact. The host's testes are repopulated by introducing a primitive germ cell population from a donor. The invention can be applied to birds. Thus, Brinster meet all of the limitations of these claims and clearly anticipate claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinster (filed May 31, 1996, US Patent No. 5,817,453), taken with Withers, et al. (1974, Radiation Research 57, 88-103).

Claim 2 is to a range of radiation doses that can be used on the acceptor cock's testicle, whereby the testicle is sterile, yet structurally intact. Furthermore, the dose is not lethal to the cock. Claim 3 is to a specific dose that is ideal in making sterile, intact testicles and is not lethal to the cock. To optimize the irradiation conditions that would yield a sterile, structurally intact testicle and not be lethal to the animal, a titration of the doses was carried out.

Brinster teaches that a male animal's testicle can be sterilized, yet be left structurally intact through a variety of methods. Included in these methods is radiation, a "suitable" (column 5, line 11) "known" (column 5, line 11) method which is preferable (column 5, line 14) to a number of other methods that was listed. Brinster also teaches that the method can be applied to birds. However, Brinster does not teach how to use radiation to sterilize the testicle, nor does

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Brinster teach that one way of optimizing the dose of radiation on the testicle can be achieved through titration.

Withers et al. teaches that increasing doses of radiation on mouse testicles results in decreasing numbers of spermatogenic colonies (page 92, paragraph under heading of "single doses", also see Figure 2).

While Withers et al. did not show doses that sterilized the testes, it would have been obvious to an ordinary artisan at the time of the instant invention to do a dose response study, where one could extrapolate and test the range of doses that would be minimally enough to sterilize a testicle and maximally enough to sterilize a testicle but not have lethal effects on a cock, given the teachings of Withers et al. demonstrating that increasing doses of radiation decreases the number of spermatogenic colonies, in view of Brinster for teaching that radiation is one routine way of creating a sterile, yet structurally intact testicle. Motivation is provided by the knowledge that the radiation is one way of sterilizing testicles and that through titration, an appropriate range of radiation doses which can sterilize a testicle and not be lethal can be found. Furthermore, Brinster states that the use of radiation to sterilize, yet maintain the structure of a testicle is "suitable," "known," and preferable.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone

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number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

Joe Wootard
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